

REMARKS

The office action of September 10, 2003 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Claims 1-42 remain in this application. By this amendment, claims 34 and 35 have been cancelled without prejudice or disclaimer. Claims 36 and 37 have been amended.

Applicants acknowledge with appreciation the Examiner's indication that dependent claims 18-20, 28-29 and 42 would be allowable if rewritten in independent form including the limitations of their respective base claims and any intervening claims. Given the allowability of the base claim from which these claims depend, as explained below, Applicants have maintained these claims in their dependent form.

Michelle Is Not Prior Art to Many of the Claims

United States Patent No. 6,520,922 to Michelle (Michelle) is applied in many of the asserted rejections. However, Michelle is not applicable as prior art to many of the claims of the present application, because Michelle was filed after the priority date of the present application for the subject matter of these claims. In particular, the present application claims priority to provisional application No. 60/223,036 filed Aug. 4, 2000. Michelle was filed on March 13, 2001, which is after the filing date of the provisional application.

35 U.S.C. § 102(e) Rejections

Claims 1, 4, 5, 9, 12, 30-31, 33 and 41 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Michelle. Applicants respectfully traverse and submit that Michelle provides no disclosure or utilization of tensegrity principles as claimed in at least independent claims 1, 31 and 33, or a method for adjusting the size of a female condom including adjusting a spacing between an external and an internal biasing member as recited in independent claim 41. In any event, Michelle is not prior art to claims 1, 4, 5, 9, 12, 30-31, 33 and 41 of the present application, because the subject matter of these claims is supported by the provisional application to which the present application claims priority, and Michelle was filed

after the provisional application. Accordingly, Applicants respectfully request that the rejections of these claims be withdrawn.

35 U.S.C. § 102(b) Rejections

Claims 34-36 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,805,604 to Sperry (Sperry). Applicants respectfully traverse. Claims 34 and 35 have been cancelled without prejudice or disclaimer in favor of claim 36 rewritten in independent form to include the subject matter of claims 34 and 35 and to more clearly define the subject matter applicants regard as their invention.

The present invention of claim 36 provides a convenient pre-packaged assembly of a female condom with an inserter device that is in a ready-for-use condition, and in which the distal end and proximal end of the female condom are within the inserter device prior to deployment. Figs. 9A-9C in the present application show such an assembly according to an embodiment of the invention. As shown, an inserter device 49 includes a plunger 51 that is advanceable in an outer housing 53. A female condom 31 is disposed within the inserter device 49. According to the embodiment shown, distal pouch section 45 is retained within outer housing 53, and upon deployment, is pushed out of outer housing 53. As also shown, outer ring 29 is retained within plunger 51. Because the pre-packaged assembly is self-contained and ready-for-use, a user can quickly and conveniently use it to deploy female condom 31. Further, because female condom 31 is retained within plunger 51 and outer housing 53, it does not need to be handled by the user for deployment.

As amended, independent claim 36 recites an assembly comprising an inserter device that includes a tubular housing and a plunger member advanceable within the housing, as well as a female condom carried within the tubular housing in a collapsed condition. Claim 36 further recites that a proximal end of the female condom extends within the plunger member, and that when the plunger member is advanced within the tubular housing, a distal end of the female condom generally opposite the proximal end is pushed out of the tubular housing. Thus, the distal end and proximal end of the female condom are within the inserter device prior to deployment.

In contrast, Spery discloses a female condom insertion assembly that is less convenient for use, and which includes a portion of the condom disposed outside of the insertion assembly prior to deployment. As shown in Fig. 2 of Spery, a closed-end 1(a) of the condom body is placed into insertion tube 4, and a rear portion 1(b) "extends outside the front portion 4(a) of the insertion tube 4, and is rolled up around the rings 2 and 3." Col. 3, lines 62-64. An applicator means such as a plunger or canister of compressed air is received by a rear portion of the insertion tube for discharging the front portion of the female condom disposed within the insertion tube from the front end of the insertion tube. See col. 4, lines 13-17 and 47-50, and Figs. 4-6. Thus, Spery teaches that a first end of the female condom is disposed within the insertion tube and that the opposite second end is disposed outside of the insertion tube.

Therefore, Spery does not disclose or suggest an insertion assembly in which a proximal end of the female condom extends within a plunger member and in which the plunger member pushes a distal end of the female condom disposed generally opposite the proximal end out of the tubular housing as the plunger member is advanced within the tubular housing. Thus, the features of claim 36 are not shown or fairly taught by Spery. Accordingly, Applicants respectfully submit Spery does not anticipate claim 36.

35 U.S.C. § 103(a) Rejections

Claims 2-3, 6-8 and 10-11 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Michelle. Claims 13-17 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Michelle in view of U.S. Patent No. 6,569,083 to Kassman (Kassman). Claims 22-27 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Michelle in view of U.S. Patent No. 5,325,871 to Reddy (Reddy). Claim 32 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Michelle in view of a reference cited by the Examiner as "Wall;" however, no such reference was included in the Examiner's PTO-892 form or in the Applicant's Information Disclosure Statement submitted previously. Claims 37-40 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Spery in view of Michelle. Applicants respectfully traverse these rejections.

The present invention pertains generally to a female condom that provides substantial stability, both externally and internally, of a woman's vagina. Stability of the condom is achieved utilizing tensegrity principles in which tension and compression members join in a structure that balances these forces. For example, as shown in Figs. 4 and 5 of the present application, when female condom 19 is inserted in a woman's vagina, inner ring 31 and outer ring 29 are pushed apart to cause "a 'tenting' of proximal section 43 against the introitus 39" Paragraph 54, page 5, lines 1-2. This provides stable retention of the condom during use. The 'tenting' occurs because "[i]ntroitus 39 tends to collapse the vaginal walls so as to exert a uniform inward compressive force on proximal pouch section 43, and inner ring 31" (Paragraph 54, lines 4-6), which pushes inner ring 31 distally within the vaginal canal and thereby places proximal pouch section 43 in tension between inner ring 31 and outer ring 29 disposed outside the vagina. Placing the proximal section 43 in tension causes it to tent against introitus 39, and to thereby stably retain the condom in place during use.

Claim 1, the base claim from which each of rejected claims 2-3, 6-8, 10-11, 13-17, 21 and 22-27 depends, is directed to a female condom employing tensegrity principles for use in a woman's vagina. Claim 1 recites a female condom comprising a pouch, an external biasing member, and an internal biasing member including a proximal portion. The proximal portion extends between the open end of the pouch expanded by the external biasing member, and the internal biasing member. To provide a stable condom based on tensegrity principles for use in a woman's vagina, claim 1 further recites "when the condom is installed within a woman's vagina, [the inner biasing member is] pushed distally by the introitus to create a force pulling against the outer biasing member, to thereby tent the proximal pouch portion against the introitus." Tenting of the proximal pouch portion according to tensegrity principles increases stability of the condom.

In contrast, Michelle discloses a device for collecting animal semen that does not disclose or suggest the use of tensegrity principles. As shown in Fig. 1, the device 20 includes a vulva ring 28 and an inner vaginal ring 30 that are both sized to be larger than the female animal's vaginal canal. In use, the "vulva ring 28 prevents device 20 from being forced (by the male's penis) completely into the vagina 500, and the inner vaginal ring 30 prevents device 20 from

unwantingly exiting the vagina 500.” Col. 3, line 66 – col. 4, line 2. The device 20 of Michelle is retained within the animal’s vaginal canal by interference between inner ring and the walls of the vaginal canal, and interference between the vulva ring and the animal’s vulva. As taught by Michelle, these rings prevent the condom from completely entering the vagina or from unwantingly exiting the vagina. However, Michelle does not teach or suggest stable retention of the condom using tensegrity principles, such as tenting a proximal pouch portion against the user’s introitus as recited in claim 1.

Thus, Michelle does not disclose or suggest a female condom as recited in claim 1 or claims depending therefrom.

Claims 2-3, 6-8 and 10-11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Michelle. Applicants respectfully submit that these dependent claims are allowable over Michelle based at least upon the above-noted shortcomings of Michelle with regard to the subject matter of claim 1.

In addition, Applicants respectfully submit that remaining dependent claims 2-3, 6-8 and 10-11 are further allowable over Michelle in view of novel features recited therein. For example, these claims recite a female condom with features having certain dimensions related to the dimensions of average adult women. For instance, because female condom 19 as shown in Figs. 4 and 5 engages the introitus 39 of a woman using tensegrity principles, the inventors recognized that the introitus dimensions of average adult women could be used advantageously to improve retention of the condom using tensegrity principles across a large percentage of the population of adult women. For example, with regard to some of these dimensions, the specification states:

It is believed that, on average, adult women will have an introitus 39 with a total depth of tissue of about 2.25. An untensioned spacing (a) of 3.25 will provide, in use, a spacing between the rings approximately equal to the 2.25 total depth of tissue ... A somewhat larger inter-ring spacing, within the range of 3.75-5.0, and most preferably 4.25, has since been found desirable to avoid adverse influences of the introitus on the ability of the inner ring to open upon insertion.

Paragraph 51, lines 8-19.

Michelle teaches sizing the female condom according to dimensions of the female animal, rather than for a woman. For this additional reason, Applicants respectfully submit that dependent claims 2-3, 6-8 and 10-11 are patentable over Michelle.

Claims 13-17 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Michelle in view of Kassman. Michelle is not prior art to claims 13-17 and 21, because the subject matter of these claims is supported by the provisional application to which the present application claims priority, and Michelle was filed after the provisional application. Thus, the rejections cannot be sustained.

Claims 22-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Michelle in view of Reddy. The Examiner recites Reddy for the teaching a foam retention member. Reddy discloses a female condom that is retained by a separately insertable retention member placed inside a pouch portion at the end of the female condom, which expands the pouch portion against vaginal walls. However, Reddy does not cure the deficiencies of Michelle as discussed above with respect to claim 1 from which claims 22-27 depend. Accordingly, Applicants respectfully submit that claims 22-27 are patentable over Michelle in view of Reddy.

Claim 32 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Michelle in view of a reference cited by the Examiner as "Wall;" however, no such reference was included in the Examiner's PTO-892 form or in the Applicants' Information Disclosure Statement submitted previously. Thus, Applicants are unable to fully respond to the rejection. Nonetheless, Michelle is not prior art to claim 32, because the subject matter of claim 32 is supported by the provisional application to which the present application claims priority, and Michelle was filed after the provisional application. Thus, the rejection cannot be sustained.

Claims 37-40 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sperry in view of Michelle. Michelle is not prior art to these claims, because the subject matter of these claims is supported by the provisional application to which the present application claims priority, and Michelle was filed after the provisional application. Thus, the rejections cannot be sustained.

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Conclusion

Based on the foregoing, Applicants respectfully submit that the application is in condition for allowance and a Notice to that effect is earnestly solicited. Should the Examiner believe that anything further is desirable in order to place the application in even better form for allowance, the Examiner is respectfully urged to contact applicant's undersigned representative at the below-listed number.

Respectfully submitted,

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